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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,330	06/26/2003	**Armand Malnoe**	115808-365	4205

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EXAMINER	
DAVIS, DEBORAH A	
ART UNIT	**PAPER NUMBER**
1655	

NOTIFICATION DATE	DELIVERY MODE
08/15/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

Office Action Summary	Application No.	Applicant(s)	
	10/607,330	MALNOE ET AL.	
	Examiner	Art Unit	
	DEBORAH A. DAVIS	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,6,8,10,11,14,16 and 23-64* is/are pending in the application.

4a) Of the above claim(s) *23-62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1,3,4,6,8,10,11,14,16,63 and 64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' response to the Office Action mailed on February 5, 2008 is acknowledged. Currently, claims 1, 3-4, 6, 8, 10-11, 14,16, and 23-64 are pending, claims 23-62 are withdrawn, claims 1, 11 and 63 are amended. Claim 2, 5, 7, 9, 12-13, 15, and 17-22 are cancelled. Claims 1, 3-4, 6, 8, 10-11, 14, 16, 63, and 64 are under consideration for examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 6, 8, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Anantharaman et al (US 6,197,361).

A composition comprising a therapeutically effective amount of a thermally extruded plant material that includes one or more phytochemical agents capable of inhibiting at least one of enzymatic and transcriptional activity to inhibit inflammation in a mammal, wherein the one or more phytochemical agents are selected from the group consisting of sesquiterpene lactones, prebiotic fibers, dietary agents, and combinations thereof, and wherein the plant material comprises at least 0.5% to less than 5% by weight of the composition and wherein the composition further comprising a component selected from the group consisting of a starch source, a protein source, a fat source and combinations thereof is apparently claimed.

The reference of Anantharaman et al., anticipates the instant claims by disclosing a gelantinized cereal product comprising chicory plant material and a protein source. The chicory plant material is an extrusion cooked (i.e. thermal) product and may be in a dried pellet form (i.e. fraction). Anantharaman discloses that chicory comprise of sesquiterpene lactones in a concentration of at least 0.5% by weight (column 1, lines 62-67, column 2, lines 21-65, claims 1-7, e.g.). Please note that because there is not a difference in the cited composition and the instant claims, the functional effects of inhibiting at least one of the enzymatic and transcriptional activity, inflammation in a mammal would be inherent.

Therefore, the reference is deemed to anticipate the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3, 11, 16, 63 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anantharaman et al as applied to claims 1, 4, 6, 8 and 10 above, and further in view of Hwang et al (US 5,905.089).

The teaching of Anantharaman et al has been set forth above but is silent with respect to particular lactones which include α-methylenebutyrolactone.

The reference of Hwang et al beneficially teaches therapeutically effective amounts of sesquiterpene lactones from plant extracts (composition) which includes α-methylenebutyrolactones that is capable of inhibiting or reducing the severity of a severe inflammatory response from enzyme activity such as cyclooxygenase and transcriptional activity derived from NF-kB as instantly claimed. The composition further includes a fat source such as olive oil, as claimed. Such active sesquiterpene lactones may be used in various combination or mixtures (see abstract, column 5, lines 1-5, lines 40-65, column 5, lines 1-9, column 6, lines 14-36, Examples 1, 4 and 5, e.g.).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to further include into the composition of Anantharaman the α-methylenebutyrolactones taught by Hwang based on the beneficial teachings of treating severe inflammatory disorders. The adjustment of particular conventional working conditions is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of the evidence to the contrary.

Response to Arguments

Applicant argues that the skilled artisan would have no reason to combine the cited references to obtain the present claims because the cited references teach away from each other and the claimed invention. Applicant argues that the reference of Ernest is directed toward topical and oral herbal composition that can be used to enhance breasts in human females by strengthening connective tissues and encouraging the growth of new cells while Hwang discloses sesquiterpene lactones obtained from plant material. Applicant argues that the reference of Hermand discloses extraction at low temperatures because low temperatures allow good preservation of the resulting extract without the addition of preservative. Applicant further argues that Hermand avoids thermal degradation of the chicory which might possibly denature the active compounds. Applicant concludes that one skilled in the art would have no reason to thermally extrude the plant material of Hermand or to combine Hermand with the cited references of Ernest and Hwang to obtain the present claims. Applicant further concludes that Hermand's hot extracted chicory extract has the same properties as cold extracted chicory and therefore teaches away from the claimed invention. Applicant finally concludes that they have obtained enhanced inhibition of enzyme activity and/or transcription activity in mammals by thermally extruding the plant material which is now required by the instant claims. These arguments has been carefully considered but not found to be persuasive of error.

In response, the cited reference of Ernest teaches plant material that includes the sesquiterpene lactones, which is a phytochemical extracted from Blessed thistle. The plant materials are thermally processed and has evidenced of anti-inflammatory properties. With respect to the reference of Hermand, the examiner only relied on this reference for the teaching of chicory plant material. Applicants' argument with respect to teaching away from the claimed invention is not persuasive because the instant claims do not recite specific temperatures but only recited thermal processing - which is now amended to "thermal extruded". The reference of Hermand used temperatures ranges of 170 degrees or less to process the chicory plant material and therefore met the previous claimed limitation of “thermally processing”.

Applicant has now amended the claims and argues that the cited references of Ernest, Hwang and Hermand all fail to disclose or suggest the amended subject matter of thermally extruding a plant material that is now required by independent claims 1, 11 and 63. The above arguments have been carefully considered but are moot in view of the new ground(s) of rejection above.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBORAH A. DAVIS whose telephone number is (571)272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Deborah A. Davis
Patent Examiner, AU 1655
August 2008

/Christopher R. Tate/
Primary Examiner, Art Unit 1655